NxStage Medical, Inc.
NxStage® Blood Tubing Set with Pre-Attached Dialyzer
510(k) Premarket Notification Submission

DEC 2 1 2012

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

Date: October 7, 2011

A. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	439 South Union Street, 5th Floor Lawrence, MA 01843 United States
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Mary Lou Stroumbos Sr. Regulatory Affairs Associate
Phone:	(978) 687-4872
Fax:	(978) 687-4750
Manufacturing Site:	MEDIMEXICO, S. DE R.L. DE C.V. Av. Valle imperial No. 10523 Parque industrial Valle Sur Tijuana, B.C., Mexico 22180
FDA Establishment Registration Number:	9616074
Sterilization Site:	Steris Corporation Isomedix Services, Inc. 1000 S. Sarah Place Ontario, CA 91761
FDA Establishment Registration Number:	Contract sterilizer

B. Device Name:

Trade/Proprietary Name:	NxStage Streamline Airless System Set with Pre-Attached Dialyzer for B. Braun Dialog Series Hemodialysis Systems
Device:	Set, tubing, blood, with and without anti-regurgitation valve
Regulation Description:	Hemodialysis System and Accessories

Regulation Medical Specialty:	Gastroenterology/Urology Devices
Review Panel:	Gastroenterology/Urology
Product Code:	KDI FJK KOC
Submission Type:	510(k)
Regulation Number:	876.5860
Device Class:	II

C. Substantial Equivalence:

The proposed NxStage Blood Tubing Set with Pre-Attached dialyzer is substantially equivalent to the identified predicates.

D. Device Description/Indications for Use:

The proposed device provides for the treatment of acute or chronic renal failure when used with the commercially available B. Braun Dialog Series hemodialysis systems. The device is a single use blood tubing set pre-attached to a high flux (permeability) hollow-fiber dialyzer.

Indications for use:

The single use blood tubing set with pre-attached dialyzer is indicated for use with the B. Braun Dialog Series hemodialysis systems for the treatment of acute and chronic renal failure.

There are no known contraindications.

E. Technological Characteristics:

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate devices.

F. Summary of Non-Clinical Test/Performance Testing - Bench

NxStage believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indication for use. Performance, verification and validation testing was conducted following the FDA's Guidance document entitled: *Hemodialysis Blood Tubing Sets - Premarket Notification [510(k)] Submissions* issued on: April 23, 2008 to characterize performance of the proposed device and the predetermined acceptance criteria was met. Results of this testing have documented that the proposed device is substantially equivalent to the predicate devices and is suitable for the labeled indication for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 21, 2012

NxStage Medical, Inc.
% Ms. Mary Lou Stroumbos
Senior Regulatory Affairs Manager
439 South Union Street, 5th Floor
LAWRENCE MA 01843

Re: K113023
Trade/Device Name: Streamline® Airless System Set with Pre-Attached Dialyzer for B. Braun Dialog® Series Hemodialysis Systems
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI, FJK, FOC
Dated: December 20, 2012
Received: December 21, 2012

Dear Ms. Stroumbos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner

Acting Director for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113023

Device Name: Streamline® Airless System Set with Pre-Attached Dialyzer for B.Braun Dialog® Series Hemodialysis Systems

Indications for Use: The single use blood tubing set with pre-attached dialyzer is indicated for use with the B. Braun Dialog Series hemodialysis systems for the treatment of acute and chronic renal failure.

There are no known contraindications.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113023